

JAN 14 2005

Custom Spine
601 Jefferson Road
Suite 208
Parsippany, NJ
07054

**510(k) Summary of Safety and Effectiveness
Custom Spine Issys Pedicle Screw System
December 29, 2004**

1. Sponsor Name
Custom Spine
601 Jefferson Road, Suite 208
Parsippany, NJ 07054
(877) 770-SPINE (7746)

2. Device Name
Proprietary Name: Issys Pedicle Screw

Common Name: Pedicle Screw System

Classification Name and Reference: 21CFR 888.3070
Pedicle Screw Spinal System
21 CFR 888.3050
Spinal interlaminar fixation orthosis

Device Product Code: MNI: Orthosis, Spinal, Pedicle Fixation
MNH: Orthosis, spondylolisthesis spinal fixation
KWP: Appliance, fixation, spinal interlaminar

3. Device Description

The Custom Spine Issys Pedicle Screw System is comprised of various types and sizes of implantable components that are assembled to create a rigid spinal construct to provide stabilization and promote spinal fusion. It is used as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. The system consists of bone screws, a polyaxial screw head, saddle pin, spinal rods, and blocker screws

and is designed to facilitate optimal screw and rod placement. Instruments made of surgical grade stainless steel are also provided which provide for the application and removal of the implant.

4. Intended use:

Custom Spine Issys Pedicle Screw System is used for the following human spine pathologies:

- Deformity
- Trauma & Tumor

When used as pedicle screw fixation system of the non cervical posterior spine (T1-S1) in skeletally mature patients, these systems are indicated for one or more of the following: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

In addition these systems are indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (grade 3 and 4) at the L5-S1 joint having fusion with autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (with pedicle placement at L3 and below) with removal of the implants after the development of a solid fusion mass

5. Identification of Legally Marketed Device

Equivalency of the Custom Spine Pedicle Screw system is based on the predicate device Moss- Miami Spinal System, Universal Spinal System, XIA Spinal System, and Optima Spinal System.

6. Comparison of Technological Characteristics

The Issys Pedicle Screw is substantially equivalent in design, materials, construction and intended use as those of the predicates identified above. Since the Issys Pedicle Screw is the same in intended use and technological characteristics as the predicate devices, the Issys Pedicle Screw does not raise any new safety and efficacy concerns when compared to these similar legally marketed devices.

7. Performance Testing

Bench testing in accordance with ASTM F1717 was conducted to demonstrate substantial equivalency to the Moss Miami Spinal System, Universal Spinal System, and Optima Spinal System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Custom Spine, Inc.
C/o Ms. Debbie Iampietro
QRC Associates
PO Box 1070
Conway, New Hampshire 03818

Re: K043522

Trade/Device Name: Custom Spine ISYSS Pedicle Screw System
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminar fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWP, MNH, MNI
Dated: December 17, 2004
Received: December 21, 2004

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

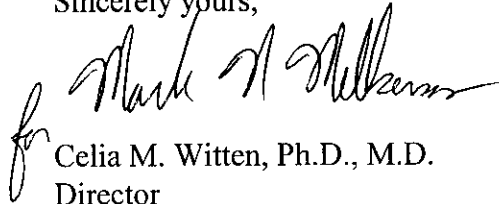
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms.Iampietro

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name. To the left of the signature is a small, stylized "for" written vertically.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative, and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Unknown

Device Name: Custom Spine Issys Pedicle Screw System

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Prescription Use X

AND/OR

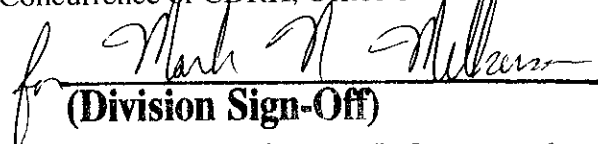
Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K043522